

Filed: February 17, 2004

Docket No.: 120.020US2

Title: METHOD AND APPARATUS FOR CALIBRATING AND
MEASURING ARTERIAL COMPLIANCE AND STROKE VOLUME

IN THE SPECIFICATION*Please amend the specification paragraph starting on page 7 line 16 as follows:*

(f) using an oscillometric signal to calibrate tonometric pressure signals in a contralateral arterial site.

In some embodiments, a calibrated radial pressure waveform $P_r(t)$ is derived from the tonometric signal $S_r(t)$ as follows:

$$P_r(t) = (1/a_r)(S_r(t) - b_r) + p$$

where $a_r = (S_r(t_D) - S_r(t_M)) / (DBP - MBP)$,

$b_r = S_r(t_M) - a_r MBP$, and

$p = \rho gh$ are calibration factors, and where

ρ = density of blood,

g = acceleration to gravity,

h = height difference between the oscillometric and the tonometric measurement sites, and is zero if the patient is supine,

MBP is oscillometric mean arterial blood pressure measured at time t_M , and

DBP is oscillometric diastolic blood pressure measured at time t_D .

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Please amend the specification paragraph starting on page 11 line 2 as follows:

In some embodiments, two pressure points are needed for calibration. In one such embodiment, MBP (mean arterial blood pressure) and DBP (diastolic blood pressure) are chosen, and respective corresponding times t_M and t_D (shifted to the appropriate time within a cardiac cycle, e.g., t_D is shifted to the nearest pulse minimum) are used:

$$S_r(t_M) = a_r \text{ MBP} + b_r$$

$$S_r(t_D) = a_r \text{ DBP} + b_r$$

$$a_r = (S_r(t_D) - S_r(t_M)) / (\text{DBP} - \text{MBP})$$

$$b_r = S_r(t_M) - a_r \text{ MBP}$$

The radial artery is approximately six inches below the brachial artery. This creates a hydrostatic pressure head that can be accommodated by a further pressure head correction factor of $p = \rho gh$, where

ρ = density of blood (= 1.03 g/cm³)

g = acceleration to gravity (= 980 cm/sec²)

$h = 6" \quad 15 \text{ cm}$

thus $p = 1.03 \text{ g/cm}^3 \cdot 980 \text{ cm/sec}^2 \cdot 15 \text{ cm} = 15141 \text{ g/cm sec}^2$

11 mm Hg if sitting (or 0 if supine)

and the calibrated radial pressure waveform $P_r(t)$ is derived from the Radial Signal $S_r(t)$ as follows:

$$P_r(t) = (1/a_r)(S_r(t) - b_r) + p$$

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Please amend the specification paragraph starting on page 13 line 11 to add a small space between r and t in the equation to avoid confusion with π (pi) as follows:

11 Examples

12 $f_{\text{infl}}(t) = k \Rightarrow n_c(t) = n_o + kt$

13 (inflation)

14 ~~$f_{\text{defl}}(t) = kn_c \Rightarrow n_c(t) = n_o + (n_{\text{max}} - n_o)e^{-rt}$~~

$f_{\text{defl}}(t) = kn_c \Rightarrow n_c(t) = n_o + (n_{\text{max}} - n_o)e^{-r t}$

15 (deflation)

16 Constant r can be obtained for a particular oscillometric device as

17
$$r = -\frac{1}{t_{.01}} \ln \frac{0.01n_o}{n_{\text{max}} - n_o}, t_{.01} \times$$

18 time to 99% complete deflation.

PRELIMINARY AMENDMENT

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Title: METHOD AND APPARATUS FOR CALIBRATING AND
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Please amend the specification paragraph starting on page 15 line 1 as follows:

- 1 Using this signal, identify the peaks and nadirs of the individual pulses using a preferred
- 2 algorithm (e.g., as in the ~~'433~~ '313 patent).

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Please amend the specification paragraph starting on page 21 line 16 as follows:

We obtain stroke volume as

Equation (15):
$$SV = \int \text{flow}(t)dt = \int A(t)v(t)dt \approx \sum_{n=1,N} t A[n]v[n]$$

where $A(t)$ is ascending aortic cross-sectional area as a function of time, $v(t)$ is ascending aortic blood velocity as a function of time, $A[n]$ and $v[n]$ are the corresponding sampled data values, t is the sampling interval, and N is the number of data points in a single cardiac cycle. Here the integral is approximated with a simple sum, but any appropriate numerical integration could be used to obtain higher precision (e.g. a high-order Newton-Cotes). $A[n]$ and $v[n]$ are obtained as

Equation (16):
$$A[n] = \sum_i h_A[n-i]P_2[i]$$

Equation (17):
$$v[n] = \sum_i h_v[n-i]P_2[i]$$

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Please amend the specification paragraph starting on page 25 line 6 as follows:

6 In some embodiments, the first method further includes (f) using an oscillometric
7 signal to calibrate tonometric pressure signals in a contralateral arterial site.
8 In some embodiments, a calibrated radial pressure waveform $P_r(t)$ is derived from the
9 tonometric signal $S_r(t)$ as follows:
10 $P_r(t) = (1/a_r)(S_r(t) - b_r) + p$
11 where $a_r = (S_r(t_D) - S_r(t_M)) / (DBP - MBP)$,
12 $b_r = S_r(t_M) - a_r MBP$, and
13 $p = \rho gh$ are calibration factors, and where
14 ρ = density of blood,
15 g = acceleration to gravity,
16 h = height difference between the oscillometric and the tonometric measurement sites,
17 and is zero if the patient is supine,
18 MBP is oscillometric mean arterial blood pressure measured at time t_M , and DBP is
19 oscillometric diastolic blood pressure measured at time t_D .

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Please amend the specification paragraph starting on page 27 line 5 as follows:

In some embodiments, the computer derives a calibrated radial pressure waveform $P_r(t)$ from the tonometric signal $S_r(t)$ as follows:

$$P_r(t) = (1/a_r)(S_r(t) - b_r) + p$$

where $a_r = (S_r(t_D) - S_r(t_M)) / (DBP - MBP)$,

$b_r = S_r(t_M) - a_r \cdot MBP$, and

$p = \rho gh$ are calibration factors, and where

ρ = density of blood,

g = acceleration to gravity,

h = height difference between the oscillometric and the tonometric measurement sites, and is zero if the patient is supine,

MBP is oscillometric mean arterial blood pressure measured at time t_M , &

DBP is oscillometric diastolic blood pressure measured at time t_D .

In some embodiments, the computer system further calculates a first compliance value based on the calibrated radial pressure waveform, estimates end-effects of the oscillometric signal, and corrects the first compliance value using the estimated end effects.